Excerpts From 180 NAC 6 for Dental Facilities

EFFECTIVE DATE NEBRASKA HEALTH AND HUMAN SERVICES
JULY 22, 2001 REGULATION AND LICENSURE 180 NAC 6
TITLE 180 CONTROL OF RADIATION

CHAPTER 6 X-RAYS IN THE HEALING ARTS

APPENDIXES

ATTACHMENT

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CHAPTER 6 X-RAYS IN THE HEALING ARTS

6-001 SCOPE AND AUTHORITY

6-001.01 180 NAC 6 establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. sections 71-3501 to 3519.

6-001.02 The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment shall be by or under the supervision of one licensed to practice the healing arts in Nebraska.

6-001.03 The use of x-ray equipment in the practice of veterinary medicine shall be by or under the supervision of an individual authorized to practice veterinary medicine in the State of Nebraska.

6-001.04 The provisions of 180 NAC 6 are in addition to, and not in substitution for, other applicable provisions of 180 NAC 1, 2, 4, 9, 10, 15, 16, 17 and 18.

6-002 DEFINITIONS: As used in Title 180, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Added filtration means any filtration which is in addition to the inherent filtration.

Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

Assembler means any person assembling, replacing, or installing one or more components into an x-ray system or subsystem. It includes adjustment of components which affect output of radiation generating equipment. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[2] or other materials having equivalent attenuation.

[1]The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, maximum 0.12 percent copper.

[2]Ibid.

Automatic exposure control means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also"Phototimer")

Barrier (See “Protective barrier”).

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Beam monitoring system means a system designed to detect and measure the radiation present in the useful beam.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968 because they come within the definitions in Section 355 (1) and (2) of that law, attached hereto as Attachment Number 6-1 and incorporated herein by this reference.

Certified system means any x-ray system which has one or more certified component(s).

Changeable filters means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

where

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

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Control panel means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.
"CT" (See "Computed tomography").

Deadman switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Direct scattered radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

Equipment (See "X-ray equipment").

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to absorb preferentially selected radiations.

Focal spot means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad shield means a protective barrier for the testes or ovaries.

Half-value layer means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Healing arts screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

HVL (See "Half-value layer").

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Image receptor support means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

Inherent filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Irradiation means the exposure of matter to ionizing radiation.

Kilovolts peak (See "Peak tube potential").

kV means kilovolts.

kVp (See Peak tube potential).

kWs means kilowatt second. It is equivalent to E + 3 kV mA s, i.e.,

$$(A)kWs = (X)kV \times (Y)mA \times (Z)s \times \frac{kWs}{E+3\ kV \times mA \times s} = \frac{XYZ\ kWs}{E+3}$$

Lead equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

Leakage technique factors means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = 100 $(V_n-V_1)/V_1$ where
V_n = No-load line potential and
V_1 = Load line potential

uC/kg means microcoulomb/kilogram.

mA means milliampere.

mAs means milliampere second.

mC/kg means millicoulomb/kilogram.

Maximum line current means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

Mobile x-ray equipment (See X-ray equipment).

nC/kg means nanocoulomb/kilogram.

Patient means an individual subjected to healing arts examination, diagnosis, or treatment.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phototimer means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

PID (See "Position indicating device").

Portable x-ray equipment (See X-ray equipment).

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Position indicating device means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Primary protective barrier (See Protective barrier).

Protective apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

> Primary protective barrier means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.
>
> Secondary protective barrier means a barrier sufficient to attenuate the stray radiation to the required degree.

Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Qualified expert with reference to radiation protection, a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (for example, persons certified in this field by the American Board of Radiology, or the American Board of Health Physics, or those having equivalent qualifications). With reference to the calibration of radiation therapy equipment, a person having in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy (for example, persons certified in Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications) or meets the minimum qualifications specified in 180 NAC 15-013.03.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiographic imaging system means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

Radiological physicist means an individual who meets the requirements of 180 NAC 15-013.01 Radiological Medical Physicist or 180 NAC 15-013.02 Radiological Health Physicist.

Rating means the operating limits as specified by the component manufacturer.

Recording means producing a permanent form of an image resulting from x-ray photons.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

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Secondary dose monitoring system means a system which will terminate irradiation in the event of failure of the primary system.

Secondary protective barrier (See "Protective barrier").

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID (See Source-image receptor distance).

Source means the focal spot of the x-ray tube.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Special purpose x-Ray system means any radiographic x-ray system which, by design, is limited to radiographic examination of a specific anatomical region.

Spot film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD means the distance between the source and the skin of the patient.

Stationary x-ray equipment (See X-ray equipment).

Stray radiation means the sum of leakage and scattered radiation.

Technique factors means the conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

5 For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

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Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Variable-aperture beam-limiting device means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

> Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
>
> Portable x-ray equipment means x-ray equipment designed to be hand-carried.
>
> Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays, including, but not limited to, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system shall be considered integral parts of the system.

X-ray subsystem means any combination of two or more components of an x-ray system.

X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

6-003 GENERAL REQUIREMENTS

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6-003.01 Administrative Controls

1. Registrant: The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of 180 NAC 6-003.01, item 1. are met in the operation of the x-ray system(s).

   a. An x-ray system which does not meet the provisions of Title 180 shall not be operated for diagnostic or therapeutic purposes, unless the Agency makes a finding that its continued use will not constitute a risk to the health and safety of the public.
   b. Registrants shall assure that individuals who will operate x-ray systems under the direction of healing arts practitioners shall meet the requirements as specified in 180 NAC 16. The Limited X-Ray System Operator shall be instructed in the radiation safety and use of the x-ray equipment as specified in 180 NAC 16-005.
   c. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information.

      (1) Patient's anatomical size versus technique factors to be utilized;
      (2) Type and focal distance of the grid to be used, if any;
      (3) Source to image receptor distance to be used;
      (4) Type and location of placement of gonad shielding to be used; and
      (5) Type and size of the film or film-screen combination to be used.

   d. Written safety procedures shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

      (1) Doors that are an integral part of room shielding shall be closed during x-ray procedures; and
      (2) The door in 180 NAC 6-003.01, item 1.d.(1). shall be posted "Close door during x-ray procedures".

   e. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

      (1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

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(2) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

(3) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

f. Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

g. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by 180 NAC 6-003.01,I item 1.k.

h. When a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 180 NAC 6-003.01, item 1., d., shall list projections where holding devices cannot be utilized;

(2) The human holder shall be protected as required by 180 NAC 6-003, item 1.e.;

(3) No individual shall be used routinely to hold film or patients;

(4) Written safety procedures, as required by 180 NAC 6-003.01 ,item 1.d.; shall indicate the requirements for selecting a holder and the procedure the holder shall follow; and

(5) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

i. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

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(1) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

(2) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

(3) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

(4) X-ray systems subject to 180 NAC 6-006 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

j. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 180 NAC 4-005, 4-048 and 4-022. In addition:

(1) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

(a) When an apron is worn, the monitoring device shall be worn at the collar outside the apron.
(b) The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by 180 NAC 4-052. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

(2) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

k. Healing Arts Screening: Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix A of 180 NAC 6. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

2. Information and Maintenance Record and Associated Information: The registrant shall maintain the following information for each x-ray system for inspection by the Agency:

a. Model and serial numbers of all certifiable components;
b. Aluminum equivalent filtration of the useful beam, including any routine variation;
c. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after June 27, 1983 with the names of persons who performed such services.
d. A scale drawing shall be available of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

(1) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

(2) The type and thickness of materials, or lead equivalency, of each protective barrier; and

e. A copy of all correspondence with this Agency regarding that x-ray system.

6-003.02 X-Ray Log: Each facility shall maintain an x-ray log or chart containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

6-003.03 Plan Review

1. Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to a qualified expert or the Agency for review and comment. The required information is denoted in Appendices 2 and 3 of 180 NAC 6.
2. The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and comment. For particle accelerator facilities the qualified expert shall be a radiological physicist.
3 The review of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 and 4-013.

6-004 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS: In addition to other requirements of 180 NAC 6-004 all diagnostic x-ray systems shall meet the following requirements:

6-004.01 Warning Label: The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

6-004.02 Battery Charge Indicator: On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6-004.03 Leakage Radiation from the Diagnostic Source Assembly: The leakage radiation from the diagnostic source assembly measured at a distance of l meter in any direction from the source shall not exceed 100 milliroentgens (25.8 uC/kg) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

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6-004.04 Radiation from Components Other Than the Diagnostic Source Assembly: The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 uC/kg) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.05 Beam Quality

1. Half-value Layer

   a. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design operating range (kVp)	Measured Potential (kVp)	Half-value layer (mm of aluminum)
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

b. The requirements of 180 NAC 6-004.05, item 1.a. will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 - 70	1.5 millimeters
Above 70	2.5 millimeters

c. In addition to the requirements of 180 NAC 6-004.05, item 1.a. all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.
d. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.
e. For capacitor energy storage equipment, compliance with the requirements of 180 NAC 6-004.05 shall be determined with the maximum quantity of charge per exposure.
f. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

2. Filtration Controls: For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 180 NAC 6-004.05, item 1.a. is in the useful beam for the given kVp which has been selected.

6-004.06 Multiple Tubes: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

6-004.07 Mechanical Support of Tube Head: The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during the exposure unless the tube housing movement is a designed function of the x-ray system.

6-004.08 Technique Indicators

1. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.
2. The requirement of 180 NAC 6-004.08, item 1. may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

6-004.09 Structural Shielding: Structural shielding shall be provided as necessary to meet the requirements of 180 NAC 4-005, 4-022, and 4-013.

6-006 RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, DENTAL INTRAORAL, VETERINARIAN, OR COMPUTED TOMOGRAPHY X-RAY SYSTEMS:

6-006.01 Beam Limitation: The useful beam shall be limited to the area of clinical interest.

1. General Purpose Stationary and Mobile X-Ray Systems

a. There shall be provided a means for stepless adjustment of the size of the x-ray field.
b. A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of

the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

c. The Agency may grant an exemption on non-certified x-ray systems to 180 NAC 6-006.01, item 1.a. and b. provided the registrant makes a written application for such exemption and in that application:
   (1) Demonstrates it is impractical to comply with 180 NAC 6-006.01, item 1.a. and b.
   (2) The purpose of 180 NAC 6-006.01, item 1.a. and b. will be met by other methods.

2. Additional Requirements for Stationary General Purpose X-Ray Systems: In addition to the requirements of 180 NAC 6-006.01, item 1., all stationary general purpose x-ray systems shall meet the following requirements:

   a. A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;
   b. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and
   c. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

3. X-Ray Systems Designed for One Image Receptor Size: Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

5. Special Purpose X-Ray Systems

   a. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
   b. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
   c. 180 NAC 6-006.01, item 5.a. and b. may be met with a system that meets the requirements for a general purpose x-ray system as specified in 180 NAC 6-006.01, item 1. or, when alignment means are also provided, may be met with either:

(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

6-006.02 Radiation Exposure Control Devices

1. Timers: Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. X-Ray Control

a. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(1) Exposures of one-half (1/2) second or less, or

(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

b. Each x-ray control shall be located in such a way as to meet the following requirements:

(1) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(2) Mobile and portable x-ray systems which are:

(a) Used in one location, i.e., a room or suite, shall meet the requirements of subdivision 180 NAC 6-006.02, item 2.b.(1).

(b) Used in different locations shall provide operator protection at the controls by adequate shielding or operator positioning at a distance from the tube head of 12 feet (3.66m).

(3) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. Automatic Exposure Controls: When an automatic exposure control is provided:

a. Indication shall be made on the control panel when this mode of operation is selected;

b. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

c. The minimum exposure time for all equipment other than that specified in 180 NAC 6-006.02, item 3.b. shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

d. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

e. A visible signal shall indicate when an exposure has been terminated at the limits required by 180 NAC 6-006.02, item 3.d. and manual resetting shall be required before further automatically timed exposures can be made.

4. Reproducibility: With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed.

$$T \geq 5(T_{max} - T_{min})$$

6-006.03 Source-to-Skin Distance: All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to greater than or equal to 30 centimeters.

6-006.04 Exposure Reproducibility: The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\bar{E} \geq 5(E_{max} - E_{min})$$

6-006.05 Radiation from Capacitor Energy Storage Equipment in Standby Status: Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 uC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

6-006.06 Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Reproducibility: When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.
2. Linearity: When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance

with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$/ X_1 - X_2 / \leq 0.10 (X_1 + X_2)$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs (uC/kg per mAs) values obtained at each of 2 consecutive tube current settings.

3. Accuracy: Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
4. Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems:

   a. There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.
   b. When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.
   c. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as $1_1/1_2$ where 1_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and 1_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

5. Beam Limitation for Portable X-Ray Systems: Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 180 NAC 6-006.01, item 1. and 180 NAC 6-006.06, item 4.
6. Field Limitation and Alignment on Stationary General Purpose X-Ray Systems: The requirements of this subpart shall apply to stationary general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c).

   a. Positive beam limitation (PBL) shall be provided whenever all the following conditions are met:
      (1) The image receptor is inserted into a permanently mounted cassette holder;
      (2) The image receptor length and width are each less than 50 centimeters;
      (3) The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray

beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(4) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;

(5) Neither tomographic nor stereographic radiography is being performed, and

(6) The PBL system has not been intentionally overridden. This override provision is subject to 180 NAC 6-006.06, item 6.c.

b. Positive beam limitation (PBL) shall prevent the production of x-rays when:

(1) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by 180 NAC 6-006.06, item 6.e., from the corresponding image receptor dimensions by more than 3 percent of the SID; or

(2) The sum of the length and width differences as stated in 180 NAC 6-006.06, item 6.b.(1), without regard to sign exceeds 4 percent of the SID.

c. If a means of overriding the positive beam limitation (PBL) system exists, that means:

(1) Shall be designed for use only in the event of PBL system failure or if the system is being serviced; and

(2) If in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator;

(a) Shall require that a key be utilized to defeat the PBL;

(b) Shall require that the key remain in place during the entire time the PBL system is overridden; and

(c) Shall require that the key or key switch be clearly and durably labeled as follows:
FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

d. Compliance with 180 NAC 6-006.06, item 6.b. shall be determinedwhen the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 180 NAC 6-006.06, item a. are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

e. The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

f. The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in 180 NAC 6-006.06, item 6.b. then any change of image receptor size or SID must cause the automatic return.

7. Timers: Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

a. Except during serial radiography, the operator shall be able to terminate the exposure at anytime during an exposure of greater than one-half second. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

b. During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6-007 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS: In addition to the provisions of 180 NAC 6-003 and 6-004, the requirements of 180 NAC 6-007 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 180 NAC 6-006.

6-007.01 Source-to-Skin Distance: X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than:

1. 18 centimeters if operable above 50 kVp, or
2. 10 centimeters if not operable above 50 kVp.

6-007.02 Field Limitation

1. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

   a. If the minimum SSD is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and
   b. If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

2. An open ended position indicating device shall meet the requirements of 180 NAC 6-004.03.

6-007.03 Timers: Means shall be provided to terminate the exposure at the preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

1. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
2. Reproducibility. With a timer setting of 0.5 seconds or, not less than 0.1 second, the average exposure period ($\bar{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed;

$$\bar{T} \geq 5 (T_{max} - T_{min})$$

6-007.04 X-Ray Control

1. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.
2. Each x-ray control shall be located in such a way as to meet the following requirements:

    a. Stationary x-ray systems installed after June 27, 1983 shall be required to have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in the protected area during the entire exposure; and
    b. Stationary x-ray systems installed prior to June 27, 1983, the operator shall remain in a protected area which permits compliance with 180 NAC 4-005 4-022, and 4-013 and
    c. Mobile and portable x-ray systems which are:

        (1) Used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of 180 NAC 6-007.04, item 2. a. and 6-007.04, item 2.b.; or
        (2) Used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirements of 180 NAC 6-007.04, item 2.c.(1) or be provided with a 6.5 feet (1.98m) high protective barrier which is placed at least 6 feet (1.83m) from the tube housing assembly and at least 6 feet (1.83m) from the patient; or
        (3) Used to make an exposure(s) of a patient at the use location shall meet the requirement of 180 NAC 6-007.04, item 2. c. (1) or (2) or be provided with a method of x-ray control which will permit the operator to be at least 12 feet (3.66m) from the tube housing assembly during an exposure.
        (4) For those x-ray systems used infrequently to make an exposure(s) of a patient at the use location, it shall be provided with a method of x-ray control which will permit the operator to be at least 6 feet (1.83m) from the tube housing assembly or the patient and be out of the primary beam during the exposure.

3. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

6-007.05 Exposure Reproducibility: The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, that the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{max}):

$$\bar{E} \geq 5 (E_{max} - E_{min})$$

6-007.06 Administrative Controls

1. Patient and film holding devices shall be used when the techniques permit.
2. The tube housing and the position indicating device shall not be hand-held during an exposure.

3. For intraoral radiography, the x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 180 NAC 6-007.02, item 1.
4. Dental fluoroscopy without image intensification shall not be used.

6-007.07 Additional Requirements Applicable to Certified Systems Only: Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.
2. Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product, obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$\left| \bar{X}_1 - \bar{X}_2 \right| \leq 0.10 \, (\bar{X}_1 + \bar{X}_2)$$

where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.
3. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
4. Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."
5. Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of 180 NAC 6-004.05, item 1.

APPENDIX 6-A

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and adddress of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

3. Description in detail of the x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of Title 180.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

10. The qualifications of each individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.

1. The plans should show, as a minimum, the following:

   (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

   (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

   (c) The dimensions of the room(s) concerned.

   (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

   (e) The make and model of the x-ray equipment and the maximum technique factors.

   (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the x-ray system(s).

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

APPENDIX 6-C

DESIGN RECOMMENDATIONS FOR AN OPERATOR'S BOOTH

1. Space Requirements:

   (a) The operator shall be allotted not less than 7.5 square feet (0.697 m^2) of unobstructed floor space in the booth.

   (b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

   (c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

   (d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette not reach the operator's station in the booth.

2. Structural Requirements:

   (a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

   (b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

   (c) Shielding shall be provided to meet the requirements of 180 NAC 4.

3. X-Ray Control Placement:

   The x-ray control for the system shall be fixed within the booth and:

   (a) Shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examining table.

   (b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

   (a) Each booth shall have at least one viewing device which will:

      (1) Be so placed that the operator can view the patient during any exposure, and

      (2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room can not be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

   (b) When the viewing system is a window, the following requirements also apply:

(1) It shall have a viewing area of at least 1 square foot (0.0929m^2) with the lower edge of the window at least 4.5 feet (1.37m) above the floor.

(2) The distance between the nearest edge of the window and the open edge of the booth shall not be less than 18 inches (0.457m).

(3) The glass shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of 180 NAC 6, Appendix 6-B, 4.(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of 180 NAC 6, Appendix 6-C, 4.(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.